REMARKS

In the office action mailed May 6, 2003, claims 51-107 were pending for consideration, and the Examiner took the following actions:

(a) claims 51-93, 99-101, and 106 were rejected under 35 USC 112, first paragraph for including the language "without added water" and "of about" in the claim language; and

(b) claims 51-107 were rejected under 35 USC 103(a) as being unpatentable over U.S. Patent No. 4,837,381 (hereinafter "Steber").

As per the arguments and amendments contained herein, reconsideration and allowance of all of the pending claims is respectfully requested. No new matter has been added by amendment. The Applicant acknowledges that the Examiner has removed all rejections and objections previously issued, other than those cited in (a) and (b) above.

REJECTIONS UNDER 35 USC 112, FIRST PARAGRAPH

The Examiner has rejected claims 51-93, 99-101, and 106 under 35 USC 112, first paragraph. Specifically, claims 51-93 and 106 were rejected for the inclusion of the phrase "without added water" in the claim language. This phrase has been removed, and replaced with language that states "said microencapsulated particles being formed without dissolving or dispersing the core material or oil with solvent." This limitation is believed to more accurately state that the claimed processes cause the formation of the microencapsulated particles without the requirement of an aqueous phase or other solvent phase, such as to form an emulsion or other solvent solution or dispersion. In other words, the core material does not need to be solubilized or dispersed to be encapsulated by the oil. Support for this amendment can be found in the Examples where complete compositions are fabricated and tested for a release profile without the requirement of the use of solvent for dissolving or dispersing the components. Reconsideration is respectfully requested.

With respect to the rejections related to the use of the phrase "of about," these phrases have been removed. Additionally, the range of from 3% to 50% by weight in these rejected claims has been amended to comport with the ranges originally filed,

namely from 3% to 30% by weight. Reconsideration of these rejections is respectfully requested.

REJECTIONS UNDER 35 USC 103(a)

Before discussing the obviousness rejections herein, it is thought proper to briefly state what is required to sustain such a rejection. The issue under § 103 is whether the PTO has stated a case of *prima facie* obviousness. According to the MPEP § 2142, the Examiner has the burden and must establish a case of *prima facie* obviousness by showing some motivation in a prior art reference to modify that reference to teach all the claim limitations in the instant application. The Applicants respectfully assert the Examiner has not satisfied the requirement for establishing a case of *prima facie* obviousness in these rejections.

The Examiner has rejected claims 51-107 under 35 USC 103(a) as being unpatentable over Steber. The Applicants have amended the independent claims to clarify the core material and oil is mixed in a high shear mixture until microencapsulated particles are formed. The amendments to claims 51, 65, 80, and 106 are supported in the specification as originally filed, by Examples 2 and 3. Claim 94 was likewise amended, and includes a limitation that the pharmaceutical composition is a sustained-release pharmaceutical composition (as stated in the title), and that the animal or vegetable oil is present at from 3% to 20% by weight of the sustained-release pharmaceutical composition.

Steber teaches compositions of fat or wax having melting points higher than 40°C with an active material for slow release compositions (col. 2, ln. 15-59), mixing such compositions (col. 5, ln. 32-35), and "forming microspheres of the resulting mixture by a variety of techniques such as emulsifying or atomizing the mixture or by processing the mixture of ingredients and molten fat, wax or mixture thereof mechanically and cooling, for example utilizing a centrifugal disc" (col. 5, ln. 35-40). The reference also states the mixture is homogenous, sprayed through a nozzle, and "the microspheres are formed as the molten droplets cool and are collected on a series of sieves in the desired size range of about 45 to 180 microns" (col. 6, ln. 8-17). Steber does not teach mixing in a high shear mixer until the microencapsulated particles are formed.

Conversely, the present process claims require the use of a high shear mixer. A high shear mixer is known generally in the art to include mixers that produce unique mixing action. The action can be created by the movement of the elements that produce intense, but gentle intermingling of materials. This results in mechanical mixing of materials in a fluidized bed. The mixing elements are typically suspended at intervals along the mixer shaft, and the size, shape, and movement of the mixing apparatus is designed to force the product into appropriate components of axial and radial motion. In one example of a high shear mixer, the unique mixing action is accomplished by a horizontal shaft which revolves at a high rate of speed, rapidly projecting and hurling the mix materials away from the vessel wall into free space, filling the entire vessel. This type of mixing action causes the materials to crisscross in the direction of the vessel walls and inversely back again, providing a high volume rate of material transfer throughout the entire length of the vessel. Speeds of these mixers can be from 600 to 2000 RPMs, which is much higher than typical mixers, as claimed in claim 80. Support for the use of a high shear mixer can be found on pages 6 and 7 of the specification as originally filed.

Additionally, with respect to composition claim 94, the animal or vegetable oil content has been amended to a range from 3% to 20% by weight of the sustained-release pharmaceutical composition. This, in conjunction with the clarification that the sustained-release pharmaceutical composition is in an oral dosage form, such as in the form of tablets, capsules, beads, granules, aggregates, powders, gels, solids, semi-solids, and suspensions, clearly distinguishes this claim from that taught or suggested by Steber. Support for oral dosage forms can be found on page 11, second paragraph.

Returning to further discussion regarding Steber, that reference identifies that the oil and active ingredient are mixed, and the mixture is processed by a "variety of techniques" to achieve the resultant particles. In support, Steber provides emulsifying, atomizing, and mechanical processes such as utilizing a centrifugal disc for particle formation. Accordingly, the particles are not formed during the mixing stage. In other words, since the homogenous mixture, not particles, is sprayed, the particles only form after the process of spraying, which is different from the claimed invention. Also, Steber specifically states that after spraying, "[t]he microspheres are formed as the molten droplets cool and are collected on a series of sieves." A plain reading of Steber identifies the microspheres are formed after spraying as the droplets

cool and are collected, which precludes particle formation during mixing. In addition, Steber does not provide any motivation to make a modification to arrive at mixing a core material and an oil in a high shear mixer until microencapsulated particles are formed.

The Applicant also asserts the Steber molten droplets cool while on a series of sieves, as previously quoted above. The Steber specification exemplifies microsphere formation after spraying, which requires a surface for spraying onto because of the time it would take a molten droplet to cool before becoming a microsphere. When a molten homogenous liquid is sprayed into the air, microspheres would not necessarily form spontaneously, as a surface provides a controlled environment for cooling and collecting particles. According to the plain language of Steber, the molten liquid droplet is required to be collected on the sieves during the decrease in temperature necessary for microsphere formation, which further shows the Steber microspheres are not formed during mixing in a high shear mixer. Also, it is well known to one of ordinary skill in the art that sieves of specific sizes are used to classify microspheres. Accordingly, Steber teaches the microspheres form while cooling on the sieves. Therefore, the limitation "that no classification step is performed during the microencapsulation process" is violated by collecting the droplets on the sieves while the microparticles are forming.

n.o because particles are formed in the body

Also, Steber states in Example 1 that the mixture used to form the particles is homogeneous. A plain reading of "homogeneous mixture" requires the mixture to be uniform throughout, which precludes the inclusion of microencapsulated particles. The instant application claim limitation of "microencapsulated particles" is contrary to a homogenous mixture because, in homogeny, there is consistency throughout the composition, which precludes any type of substantial encapsulation. Encapsulation connotes at least two distinct parts, where one at least partially encapsulates the other, thereby preventing a mixture containing microencapsulated particles from being homogeneous. Therefore, spraying a homogenous mixture precludes the mixture being sprayed from having microencapsulated particles contained therein.

Since Steber teaches homogenous mixtures, processing a mixture for particle formation, and particle formation after spraying a homogenous mixture onto sieves, the Examiner has not established a case of *prima facie* obviousness. Thus, the Applicants respectfully request withdrawal of the rejections to all pending claims.

In view of the foregoing, Applicants believe that claims 51-107 present allowable subject matter and allowance is respectfully requested. If any impediment to the allowance of these claims remains after consideration of the above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone Gary Oakeson, or in his absence the undersigned attorney, at (801) 566-6633, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 6th day of Aug., 2003.

Respectfully submitted,

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